

Appln No.: 09/678,357
Amendment Dated: November 5, 2004
Reply to Office Action of August 5, 2004

REMARKS/ARGUMENTS

This is in response to the Office Action mailed August 5, 2004 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Claims 39-43 have been canceled, rendering moot the rejections directed to these claims. Thus, claims 14, 15, 18-30 and 32 are now presented for examination. It is noted that no rejection was expressly applied to claims 19-29 in the prior office action, although there was also no indication that these claims were allowable.

Claim 14 has been amended to make it clear that the number referred to in the final paragraph is the same number obtained in the preceding paragraph, and to correct a grammatical error.

Claims 14, 15, 18, 30 and 32 stand rejected under 35 USC § 103 as obvious over the combination of Oksanen et al. and Ma et al. The references teach several tests related to gastritis, and the Examiner says that performing multiple tests is obvious, even though neither reference actually indicates that spending more money and effort to perform multiple tests would lead to any improvement in results. The Examiner has not cited any evidence that the knowledge from the references of multiple possible assays which are compared, but never shown to be combined, supports a conclusion of performing any combination of these assays, let alone the specific combination claimed. The mere statement that the Examiner is relying on the combination of references, not individual references, (Office Action, Page 6) is not sufficient to create a *prima facie* case of obviousness. Indeed, as the Courts have observed, "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 140, 231 USPQ 644, 647 (Fed. Cir. 1986) (citing *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)). "[T]he factual inquiry whether to combine references must be thorough and searching." *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Here, the references only provide the individual elements, and this is not enough. *Ex Parte Hiyamizu*, 10 USPQ 2d 1393, 1394 (POBAI 1988) ("Citing references which merely indicate the isolated elements ... are known is not a sufficient basis for concluding that the combination of elements would have been obvious.")

Further, the Examiner states, without support in any relevant art, that "limitations such as higher or lower levels of the indicators or calculating ratios of the indicators are being viewed as limitations of optimizing experimental parameters." The Examiner further states, again without any evidentiary support, that "it is well known in the art of medicine and clinical diagnosis to evaluate multiple tests done separately in combination to arrive at diagnosis and type of disease,

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i.e., gastritis." Thus, the very basis for the combination of references, and the assertion that additional limitations in the claims are also obvious is unidentified art and unsubstantiated assertions. This is improper. To the extent this rejection is maintained, Applicants submit that the Examiner must provide evidence that whatever modifications of this type he says would have been obvious were known in the art to be result dependent variables, and of the "fact" that he asserts is well known. Absent such a showing, the Examiner is relying on unestablished facts, of which he may not merely take notice. *See, In re Ahlert*, 165 USPQ 418, 420-21 (CCPA 1970). Demand for evidence supporting the Examiner's assumptions is hereby made.


Applicants respectfully submit, however, that even the Examiner's statement of what would have been obvious does not reach the claims as presently presented. Claim 14 recites the

steps of multiplying the level of pepsinogen I by the level of *Helicobacter pylori* antibodies to get a number, and comparing the number to a number calculated similarly for the normal population.

Whether or not it is true that determination of a ratio between known experimental values may be generally obvious, nothing can be said without substantial specific explanation concerning the product of two values. In the present case, there is nothing in the art that suggests that taking the product of any two numbers would be a desirable step, or provide information of diagnostic significance. Thus, the claimed invention, as a whole, is not rendered obvious by the cited art.

For the foregoing reasons, Applicants submit that the claims of this application are in form for allowance. Favorable reconsideration and allowance of all pending claims are therefore urged.

Respectfully submitted,



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